

AMENDMENTS TO THE SPECIFICATION

The paragraph beginning on page 15, line 23, is being amended as follows:

The present invention also provides a process for preparation of the lyophilized formulation as described above. According to the process, an oil-in-water emulsion comprising a bacterial component, an oil, a surfactant, an excipient, a stabilizer, etc. is first prepared before lyophilization. Such an oil-in-water emulsion is prepared by, for example, adding a bacterial component at a concentration as described above to an oil at a concentration as described above, adding further an aqueous solution of a surfactant, an excipient, a stabilizer and another additive to the mixture, and then emulsifying the resultant mixture until forming an oil-in-water emulsion with an average particle diameter as described above with a dispersing or emulsifying device such as a Potter-Elvehjem type homogenizer, a homomixer, an ultrasonic homogenizer, ~~Microfluidizer~~ MICROFLUIDIZER (trade name), ~~Nanomizer~~ NANOMIZER (trade name), ~~Ultimizer~~ ULTIMIZER (trade name), Gaulin homogenizer type high pressure homogenizer, and the like. If necessary from viewpoint of preparation, an additive such as an excipient, or a stabilizer may be added to the oil-in-water emulsion that have been prepared as shown above.